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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/809,021	03/16/2001	Hubert Metzner	06478.1452	5147
22852	7590	03/10/2006	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			MELLER, MICHAEL V	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/809,021	<b>Applicant(s)</b> METZNER ET AL.	
	<b>Examiner</b> Michael V. Meller	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 20-24, 27-30, 33 and 49-61 is/are pending in the application.
- 4a) Of the above claim(s) 20-24, 27-30 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 49-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

The restriction of record is maintained. Claims 20-24, 27-30, 33 are withdrawn for the reasons of record.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 49-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification for “after at least 12 months” , “after at least 24 months” and “measured by a coagulation test with a fibrinogen substrate, is at least 70 %” as claimed in claim 49, for example. Each of the “at least” percentages of

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claims 49-54 have no support in the specification either. Specific ranges are shown in the specification but not the language "at least 90 %", for example. Further, there is no support for "sugar alcohol at a maximum concentration of 2% (w/v)". There is support for specific amounts of mannitol but not this as claimed.

Applicant argues that the support for "at least 70 %" and the other percentages have support but the support the specification teaches are for ranges 70-80% which does not support "at least 70%", see specification, page 3, first full paragraph. The specification does not find support for claim 58 either. The mannitol is used at 1 and 2 % amounts but that does not provide support for , "sugar alcohol at a maximum concentration of 2%". Nowhere in the specification can such support be found.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 49-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allary et al. or Lorne et al. taken with Hanada et al., Brezniak et al. and Altshuler.

Allary and Lorne each teach that thrombin is eluted off a benzamidine-Sepharose column. Thrombin and benzamidine would be together in the eluate. Since they elute using benzamidine in a competitive elution then a complex of thrombin-benzamidine as in the present claims would have been formed.

Allary and Lorne do not teach using the other ingredients in the composition such as lysine, calcium chloride, NaCl, etc.

Hanada teaches that thrombin can be therapeutically viable using many of the other components in the composition and that p-aminobenzamidine and benzamidine are interchangeable, see all of col. 4. Altshuler teaches that therapeutically viable thrombin can also include other components in the composition such as lysine, NaCl, glycerol, see col. 3, lines 13-30, example I. Brezniak also teaches that therapeutically viable thrombin can include other ingredients in the composition such as calcium chloride, polyethylene glycol, NaCl, see abstract, page 847.

Thus, it would have been obvious to add the other components (NaCl, lysine, glycerol, calcium chloride, etc.) to the composition of thrombin and benzamidine of Allary and Lorne since it is well known in the art as is established by Altshuler, Brezniak and Hanada that the other components are well known to be added to therapeutically viable compositions of thrombin.

The percentages of activity of the enzyme are inherent to that enzyme, thus the conditions of claims 39-45, 48 are inherent to the preparation. The same is true for the amount of polyalcohol. The same ingredients are used in the preparations of the references as that which applicant uses, thus the inherent activities of the preparations will be the same.

Applicants argue that the since the board stated on page 7 of their decision that "[w]e do not, however, interpret the claim to require that the preparation be stable when stored in liquid form, or that it be virus-free, or that it be sterile" that now applicant is entitled to the present claims. This is not agreed with. After the board made the above quoted statement they also said, "[w]hile those properties may be desirable for a commercial product, the absence of such properties would not render the preparation therapeutically ineffective. Therefore, they are not required by the phrase 'suitable for therapeutic purposes' when that phrase is given its broadest reasonable interpretation in light of the specification".

Thus, those characteristics do not impart patentability to the claims as applicant now suggests. And as stated above, those characteristics are inherent to the claimed composition and do not need to be explicitly stated by the references.

Applicant also argues that preparation without the added inhibitors do not have such great stability as claimed but the references do teach using the same exact inhibitors as applicant has.

Applicants argue that Lorne and Allary remove the inhibitors thus it cannot be the same preparation as claimed. Lorne and Allary teach a solution which contains the

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inhibitor and the enzyme. Applicant is claiming a "preparation" which is all the claims require. Applicant is **not** claiming a process. The claims read on a **product**. The same ingredients are in each. Thus, the same product as which is claimed is in the references which the board has agreed with the examiner on.

Thus, the same "preparation" as claimed is taught by the references.

Applicants continue to argue that the thrombin inhibitor was removed. They argue that only after it was removed it was used for practical use. While this is an interesting point, it does not negate the fact that the reference does teach the claimed invention. It may not teach that the final product is the claimed invention but it does teach the claimed invention. When the thrombin is on the column it contains the benzamidine, thus the combination of the two is taught by Allary and Lorne.

Applicant also argues that the references teach that benzamidine does not work well. This is not true. Benzamidine was noted as being a fine eluate and that the methyl ethyl arginine could also be used.

There is no evidence that the amount of sugar alcohol used would increase the viscosity of the thrombin preparation.

It is noted that this composition is a hemostatic (see Lorne, page 3, top) and that Lorne and Allary recognize that it can be used in a tissue glue making the preparation a constituent of a tissue glue.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael V. Meller  
Primary Examiner  
Art Unit 1655

MVM